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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/203,768	12/02/1998	JEFFRY D. WATKINS	P-IX-2947	4594

23601 7590 12/03/2003
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/203,768

Applicant(s)

WATKINS ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,6,47 and 48 is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 47-48 are pending.
Claim 6 has been amended.
2. Claims 1-6 and 47-48 are under examination.
3. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.

Claim Objection

4. Claim 6 is objected to because the term "of" in line 1 should be "or".
Appropriate correction is needed.

Rejections Withdrawn

5. The rejection of claim 6 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to the claim.

Response to Arguments

6. The rejection of claim 5 under 35 U.S.C. 112, first paragraph, is maintained.
The response filed 9/9/03 has been carefully considered but is deemed not to be persuasive. The response states that applicant has previously set forth multiple uses such as administration or detection of neoplastic cells and numerous teachings for the preparation and use for treatment or diagnosis and have provided extrinsic evidence

Art Unit: 1642

showing treatment of cancer with 18 monoclonal antibodies in the art (Walsh) and the treatment of cancer with antibody based pharmaceuticals composition is a developed art and the antibody claimed is specific to neoplastic cells and shows relatively little binding to normal cells and FACS was used to demonstrate binding of the antibody to neoplastic cells (see pages 6-9 of response).

In response to these arguments, the specification only teaches detection in vitro and FACS in vitro data. There is no in vivo data correlating the findings of the in vitro data. Although the antibody binds to neoplastic cells in vitro over normal cells, there is no correlation to in vivo treatment or detection. As cited in the prior art correlation to in vivo treatment or detection is unpredictable. Although there are numerous antibodies in the prior art, as cited by Walsh, as stated in the previous Office Action, while Walsh teach antibodies to tumor antigens, the antigens have been well characterized and methods for with the antibodies to these antigens bind have been shown to be successful for treatment of cancer. This is in contrast to the antigen LH11238 which the claimed antibody binds to. The specification only discloses in vitro data of binding of the antibody to tumor cells and as evidenced from the references cited in the rejection the art does not recognize a clear correlation between in vitro data and in vivo data. The antigen to which the claimed antibody binds to has not been clearly demonstrated as a target for cancer therapy or whether targeting the antigen in vivo with an antibody would result in tumor killing or treatment or detection. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which

Art Unit: 1642

would allow one of skill in the art to predict the efficacy of the claimed antibodies with a reasonable expectation of success.

In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention. Amending the claim to remove 'pharmaceutical' before composition would be sufficient to obviate this rejection.

Conclusions

7. Claims 1-4, 6, 47-48 are in condition for allowance.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703)

Art Unit: 1642


306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER